Reviewer’s report

Title: Developing an Intervention for Fall-Related Injuries in Dementia (DIFRID): an integrated, mixed-methods approach

Version: 0 Date: 04 Nov 2018

Reviewer: Ellen Freiberger

Reviewer's report:

The authors developed an intervention improving fall related outcomes for older persons with dementia by using an integrated mixed-methods approach. This manuscript targets an important topic regarding the increase of falls and dementia in older persons and will therefore add to the existing literature. Although the manuscript is of importance there are several major comments to be addressed before the manuscript can be considered for publication. Overall the length of the manuscript does exceed normal manuscript. The authors are encouraged to shorten their manuscript.

Major comments:

Title:

1. The title does not reflect the thorough full development of the intervention. The reviewer would suggest to mention either that the intervention is based on a theory or that an integrated mixed method is used.

Abstract (p 4 line 6-12):

2. In the introduction of the abstract the authors stated that they developed a theory for an intervention. It is not clear for the reviewer what the aim of the intervention should be: reduction of fall related injuries or long-term outcomes. This is only being mention later on in the abstract (line 48).
3. The authors present their stage model for development of the theory but in the abstract they do not present a "theory" but more consensus related information and components of the intervention. This information does not fit precisely the introduction in the abstract.

Background:

4. The authors use different terms for their approach: (p 5 line 39-40) is stated that effective models are missing for complex intervention and in (p 6 line 10) about theoretical mechanism whereas the authors talk about a theory in the abstract (p 4 line 19) and theory development (p 6 line 46). The reviewer would suggest to either stick to one term or define both terms and present some rational for the different terms.

5. In the introduction the authors should add a short paragraph about the different impact of falls or injurious falls. As it reads now the authors compare outcome of falls and injurious falls similar, which is not the case. Please specify why the authors are concentrating on injurious falls only.

6. Furthermore, the authors talk about fall preventive intervention in older persons with dementia but the reviewer is missing the Hauer group being mentioned there e.g. Hauer et al., 2018 Gerontology; Dutzi, I., et al., Cognitive Change in Rehabilitation Patients with Dementia: Prevalence and Association with Rehabilitation Success. J Alzheimers Dis, 2017. 60(3): p. 1171-1182; Hauer, K., et al., Physical training improves motor performance in people with dementia: a randomized controlled trial. J Am Geriatr Soc, 2012. 60(1): p. 8-15.)

7. The reviewer would suggest to split the described third goal in this manuscript (p 6 line 12-15) "the development of a logic model and intervention materials" into two separate goals. The development of a logic model is somehow different to the development of intervention materials. Furthermore, Figure 1 shows that the both points are sperated.
Methods:

8. The authors are to congratulate for their in-depth methods of developing the new intervention. Nevertheless the reviewer question the part "Theory development" (p 6 line 47) as different terms have been used before.

9. Please explain why the area of "context" "mechanism" and "outcome" (p 7 line 8-12) were chosen as they have not been mentioned before. The reviewer assumes that in the step before "grouping emerging themes" this is the result of but that has not been described. This is also the case for stating the categories "reasoning" and "resources". No information how these categories arise are given.

10. For the reviewer from the search strategies it is not clear if the authors also differentiated to setting e.g. Nursing Homes or Community-dwelling as this is going to have an impact on the development of the intervention later on e.g. with respect to possible frequency and duration as well as education of provider (p. 8 line 6-12).

11. For the reviewer it is not clear if in the Consensus meeting 1 all experts got the same information or were split right away into three groups which would make a difference. Please explain (p 9 line 22-30).

12. Please provide information if all 24 panel members responded in the Delphi Round or if some members only responded to some question and how the authors handled missing answers (pa 9 line 37-47). The reviewer wonders if the 2/3 majority would include all 24 panel members or the panel members taking part in the Delphi round.

13. Please explain how stakeholders could be informed about possible intervention if the process of intervention development was under way (p 10 line 2-14).
14. The authors are to congratulate for their methods to develop the logic model. To the current knowledge of the reviewer, no other research group has gone through such an intensive methodological way of developing an intervention (p 10 line 33-43)

15. The paragraph "preparation of intervention resources" comes for the reviewer "out of the blue" as no description of this theme has been described before (p 10 line 48-56). Please reconsider for clarification or moving to somewhere else in the manuscript.

Results

16. The literature given for the CM0 c2 is mostly based on hip fracture patient. As the authors address "injurious falls" the reviewer wonders if the authors have focused on hip fracture as the most important injury but have not stated these focus earlier in the manuscript. Please explain. (p 12 line 34-56)

17. Furthermore in the CMOc2 no information on Nursing home setting is presented. The reviewer wonders if this has not been a topic of the Delphi round.

18. The reviewer would like to suggest of rephrasing the heading of CMO c3 as the variables of interest "social isolation" and psychosocial factors could not be subsumed under comorbidities (13 line 25)

19. In addition the statement by the stakeholder is about "falls" not injurious falls adding to the confusion of what the goal of the authors are (p 13-14 line 55-6). Please review.

20. By looking at table 2 (p 14) the reviewer wonder if actually all necessary assessments are in place to obtain all the relevant information. By being familiar with fear of falling and nutrition, to the knowledge of the reviewer, no such instruments exist for older persons with dementia, or are this information obtained by proxy? Then the authors should state how the information could be obtained.
21. Although the reviewer is familiar with the OTAGO Program it is not clear how the authors relate their future intervention to the OTAGO without mentioning this exercise program before throughout their manuscript. This information should be added to the background, that the OTAGO program is most effective and used in Nursing homes. Nevertheless again, the inconsistency which setting is addressed does show up here as the quote presented is from the hospital setting or a nursing home? (p 16 line 20-36). Again, the reviewer wonders in which setting the future intervention should be applied.

22. The question about duration or ongoing support (CMO c5) does not address the international recommendation of required session to be effective e.g. Burton et al., 2015. Furthermore, this section needs shortening.

23. Interestingly to the reviewer in CMOc7 the aspect of huge fluctuation of staff is not mentioned. Did this topic not arise during the consensus meeting? Fluctuation of staff is one of the major barriers for implementing effective fall prevention programs in an EU country not UK. Please comment.

24. The section of Design and feasibility adds again to the confusion of the reviewer (p 24 line 31). As the reviewer suspected it the authors are changing from now from an intervention to prevent injurious falls to a more simple fall prevention. This has not been addressed in the background or before. Please review and comment carefully.

25. In the outcome measure section (p 25 line 24) the authors are defining, as an outcome "falls" not even injurious falls. With regard to the short intervention period (mentioned before) the reviewer doubt if the intervention will show any effects, and why the authors are not looking on functional benefits, or is this outcome measure being obtained in the feasibility study? Then please comment and add this information.
Discussion:

26. The reviewer wonders why international recommendation for fall prevention are not cited here (e.g. Sherrington et al., 2016 or Gillespie et al., 2012), as these international recommendation are setting the frame in other health care systems, and should be acknowledged.

27. The information about attendance of the panel members and response rate should be provided earlier in the method section (see comment above) (p 27 line 42-46).

Minor comments:

Please provide a short summary of the effectiveness narrative review (p7 line 30-35) as well as for the realistic synthesis (pa 7 line 40).

As not many future readers might be familiar with the approaches the authors used please specify the term "searches were carried out inductively" ( p 7 line 45).

Please spell the abbreviation of PWD (p 9 line 12) if used for the first time.

Please also spell abbreviation MDT (p 19 line 37). The reviewer assumes multidisciplinary team but is not sure.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
Yes

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I recommend additional statistical review

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